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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,924	11/06/2000	Heinrich Planck	24446	8132

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EXAMINER

PIERCE, JEREMY R

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 02/12/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/705,924

Applicant(s)

PLANCK ET AL.

Examiner

Jeremy R. Pierce

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SM
#12

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,32,34,36,38,40-43,46,49-57 and 59-73 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 30,32,34,36,38,40-43,46,49-57 and 59-73 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Amendment B has been filed on December 23, 2002 as Paper No. 11. Claims 30, 32, 34, 36, 38, 40-43, 46, 49-57, and 59-73 have been amended and are currently pending. Claims 31, 33, 35, 37, 39, 44, 45, 47, 48, and 58 have been cancelled. The amendment is sufficient to overcome the claim objections and rejections set forth in the last Office Action.

Claim Rejections - 35 USC § 112

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 recites "the surface area of the pores of a first net overlaps with the surface area of the pores of a second net roughly by half." What does this mean? How does one surface area overlap another by half?

Claim Rejections - 35 USC § 103

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4. Claims 30, 32, 34, 36, 38, 41-43, 46, 54-57, 59-63, and 65-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (WO 99/51163) in view of Eldridge (U.S. Patent No. 6,120,539).

Tormala et al. disclose a hernia mesh that comprises a rapidly degradable first layer and more slowly degradable second layer (page 3, lines 4-5). The layers are formed from knitted fabrics into a porous mesh (page 6, lines 6-9). Tormala et al. describe the fibers used to make the knitted mesh as filaments having a diameter of 50 microns (page 7, lines 1-9). Tormala et al. do not teach using exclusively monofilament fibers in the implant. Eldridge et al. disclose a prosthetic repair fabric comprising a first sheet of porous and tissue infiltratable material and a second sheet united with the first sheet (column 1, lines 44-52). Eldridge et al. teach that such two layer implants can be made from either monofilament or multifilament yarn (column 3, lines 14-15). It would have been obvious to one having ordinary skill in the art to use monofilament fibers in Tormala et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Tormala et al. teach the two layers have different pore structures, where the first layer has pores between 50 and 1000 microns (page 5, line 14) and the second layer has pores between 0.1 to 2.0 millimeters (page 5, lines 18-19). The pores of the two knitted fabrics would not be aligned with one another because of the difference in pore sizes between the two layers. Additionally, the pore sizes of the meshes would increase as the material is absorbed in the body. Although Tormala et al. do not explicitly teach the limitation of

bursting pressure, it is reasonable to presume that said limitations are inherent to the invention. Support for said presumption is found in the use of similar materials (i.e. absorbable prosthetic textile) and in the similar production steps (i.e. double layer knitting) used to produce the implant. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, it would have been obvious to a person having ordinary skill in the art to give the textile the claimed bursting pressure so that the implant could hold itself into place, since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). With regard to claim 34, Tormala et al. do not disclose the thickness of the fibers to be between 100 and 150 microns. However, modifying the size of the fibers would be modifying a result effective variable that would make the implant thicker, and thus, stronger and longer lasting. With regard to claims 38 and 43, the different pore ranges for the first and second layers would give a different binding construction. With regard to claims 55-57 and 59-63, Tormala et al. do not disclose various claimed properties such as weight per unit area, strength, bursting pressure, bursting elongation, extensibility, and tearing strength. However, modification of material to obtain desired values in these properties is well known in the art of making prosthetic textile fabrics. If not already inherent by the material of Tormala et al., it would have been obvious to one having ordinary skill in the art to modify the prosthetic textile fabric disclosed by Tormala et al. with the claimed properties in order to create a fabric with desired suitability for its intended use, since it has been held that discovering an optimum value of a result effective variable involves

only routine skill in the art. With regard to claims 66 and 73, Tormala et al. do not specifically cite using the fabric in the form of a belt for supporting the female urethra. However, it is well within the knowledge of a person of ordinary skill in the art to use prosthetic textiles in various parts of the body.

5. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view Eldridge et al. as set forth above, and further in view of Titone et al. (U.S. Patent No. 5,569,273).

Tormala et al. do not disclose knitting the mesh in a hexagonal shape. Titone et al. teach a hexagonal mesh fabric used in hernia repair that provides desired performance and physical characteristics (column 1, lines 47-61). It would have been obvious to one having ordinary skill in the art to make the prosthetic fabrics of Eldridge et al. or Tormala et al. with a hexagonal shape as a matter of design choice in providing desired strength and performance characteristics, as taught by Titone et al.

6. Claims 49, 51-53, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Eldridge et al. as set forth above, and further in view of Dumican (U.S. Patent No. 4,871,365).

Tormala et al. do teach manufacturing the layers of two different absorbable polymers that degrade at different rates, but do not teach one of the polymers be entirely non-absorbable. Dumican teaches a 50:50 mix of absorbable and non-absorbable material in a prosthetic implant (column 2, lines 17-33). It would have been obvious to one having ordinary skill in the art to modify the second layer of Tormala et al. from a slowly degrading polymer to a non-absorbable polymer, so that the material

can be used as a prosthetic in instances where a permanent implant is required, as taught to be known by Dumican.

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Eldridge et al. and Dumican as applied to claim 49 above, and further in view of Titone et al. as applied to claim 40 above.

Response to Arguments

8. Applicant's arguments with respect to the rejections have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed in Paper No. 11 have been fully considered but they are not persuasive.

10. Applicant argues that Tormala et al. do not teach the method of joining the textile fabric structures over their surface area. However, by sewing the two layers of fabric together, that is exactly what Tormala is doing. The layers become firmly interconnected upon being sewn together. Tormala et al. also disclose the fabrics may combined by knitting (Example 2).

11. Applicant argues that the overlap of ranges for the pores sizes of the two layers (i.e. 50-1000 microns and 100-2000 microns) allow the pores of the two layers to have the same size (between 100 and 1000 microns), and there is no teaching that the pores of the two layers must have a different size or be aligned. However, what about when the first layer DOES have a pores that are 50 microns in size? Or when the second layer has pores that are 2000 microns in size? The pores would not be the same size

under these scenarios. Just because it is possible that they may end up being the same size, does not mean it is required.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy R. Pierce whose telephone number is (703) 605-4243. The examiner can normally be reached on Monday-Thursday 7-4:30 and alternate Fridays 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (703) 308-2414. The fax phone numbers

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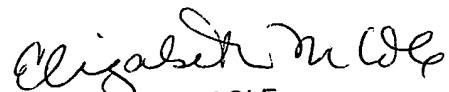
for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jeremy R. Pierce
Examiner
Art Unit 1771

February 7, 2003



ELIZABETH M. COLE
PRIMARY EXAMINER